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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,801	06/29/2001	Thomas C. Pinkerton	6794S-000019US	1264

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EXAMINER	
HAYES, MICHAEL J	

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 05/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/897,801	PINKERTON, THOMAS C.	
	Examiner	Art Unit	
	Michael J. Hayes	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *117 and 118* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *85,87-92,94-97,99-102,105-108,110-113,116,119,121-126,128,129,131-136 and 138* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 June 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 85,87-92,94-97,99-102,105-108,110-113,116-119,121-126,128,129,131-136 and 138.

DETAILED ACTION

Prosecution Reopened

The prosecution of this patent application is reopened in view of the new rejections discussed below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 85, 87, 90, 91, 94-97, 99, 105-108, 110, 116, 119, 121, 124, 125, 128, 129, 131, 134, 135, and 138 are rejected under 35 U.S.C. 103(a) as being unpatentable over GROSS. Gross discloses a method of delivering various drugs and medicine, including heparin and somatotropin (growth hormone) intradermally (3:40-41) using a single needle with an outlet at a depth of 250 gm - 2mm in a controlled manner based on needle diameter (4:10-35). Gross discloses that the delivery can be pulsatile (i.e., repeated bolus injections). It is inherent that the intradermal injections will be absorbed systemically from the dermis due to the linking of the intradermal compartment to systemic circulation via blood circulation. Furthermore, the method disclosed by Gross will inherently show improved systemic absorption relative to absorption produced upon subcutaneous bolus administration. The conclusion of improved systemic absorption is based on the evidence of record that the location of the delivery site (i.e.,

intradermal location) is the critical factor in achieving the improved systemic absorption. Upon delivering medication to the intradermal compartment, the physiology of this location causes the improved systemic absorption as compared to bolus subcutaneous injections.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 85, 87-91, 94-97, 99, 100, 101, 105-108, 110, 111, 112, 116, 119, 121-125, 128, 129, 131-135, and 138 are rejected under 35 U.S.C. 103(a) as being unpatentable over GROSS in view of D'Antonio et al. (US Patent No. 6,056,716) or Puri et al. (*An Investigation Of The Intradermal Route As An Effective Means Of Immunization For Microparticulate Vaccine Delivery Systems*, Vaccine 18 (2000) 2600-2612).

If the method disclosed by Gross does not inherently show improved systemic absorption relative to absorption produced upon subcutaneous bolus administration, it would have been obvious to one of ordinary skill in the art to modify the method to obtain improved systemic absorption relative to absorption produced upon subcutaneous bolus administration. Gross discloses a method of delivering various drugs and medicine, including heparin and somatotropin (growth hormone) intradermally (3:40-41) using a single needle with an outlet at a depth of 250 gm - 2mm in a controlled manner based on needle diameter (4:10-35). Gross discloses that the

delivery can be pulsatile (i.e., repeated bolus injections). Upon delivering medication to the intradermal compartment, the physiology of this location causes the improved systemic absorption as compared to bolus subcutaneous injections. D'Antonio and Puri disclose that medication delivered intradermally results in improved systemic absorption. D'Antonio (3:27-28, 29:3-26) teaches ID injections for growth hormones, vaccines, sera, vitamins, and nutrients. D'Antonio discloses that intradermal injection testing shows a better absorption than subcutaneous injection as evidenced by tests showing that ID is more potent than subcutaneous injections. Puri teaches better absorption by ID injections for microparticulate vaccines having better absorption than subcutaneous injections as evidenced by lower required doses when administered ID (See abstract, pg. 2601, 2607-2610). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of D'Antonio and/or Puri in the method of Gross in order to achieve a therapeutic result using less drugs. The cost savings and ability to effectively deliver scarce drugs to a larger number of people would motivate one of ordinary skill in the art to modify the method of Gross with the teachings of D'Antonio and/or Puri.

The use of nanoparticles are considered as equivalent to the disclosed use of microparticles in the prior art, and obvious to give improved absorption, particularly in consideration that the nanoparticles are even smaller than the microparticles. Additionally, in view of the large number and classes of drugs listed by Gross for delivery by the disclosed method, the use of dopamine receptor agonist would have been obvious to one of ordinary skill in the art because it is recognized as another drug. One of ordinary skill in the art would have the knowledge to apply the disclosed method to additional drugs.

Claims 92, 102, 113, 126, and 136 are rejected under 35 U.S.C. 103(a) as being unpatentable over GROSS in view of D'ANTONIO or PURI as applied to claims 91, 97, 107, 125, or 135 above, and further in view of GANDERTON et al. (US Patent No. 3,8 14,097). Gross discloses the claimed method except for using an array of needles. Ganderton discloses injecting a substance through multiple needles (1:9-40). See fig. 1. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Ganderton in the method of Gross and D'Antonio or Puri in order to facilitate the distribution of delivered drug to a patient.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (571) 272-4959. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi, can be contacted at (571) 272-4977. The fax number for submitting official papers is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh
5 May 2005

MICHAEL J. HAYES
PRIMARY EXAMINER